REMARKS

Applicant has amended claims 22, 23, 35 and 38 to remove the objected to language in view of the fact that, as clearly stated in the specification, see page 8, these tests are known to one of ordinary skill in the art. Moreover, the specification provides sufficient guidance to one of ordinary skill in the art to determine the metes and bounds of the invention and therefore it is most respectfully requested that the rejection under 35 U.S.C. 112 be withdrawn.

The rejection of claims 19-23, 25, 28, 29, 31, 35, 38 and 39 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,143,126 to Boesch et al. has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).
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> *Akzo N.V. v. International Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241 (Fed. Cir. 1986) (Claims to a process for making aramid fibers using a 98% solution of sulfuric acid were not anticipated by a reference which disclosed using sulfuric acid solution but which did not disclose using a 98% concentrated sulfuric acid solution.).

Applicant appreciates the indication in the Official Action of the specific portion of the reference relied upon in the rejection and this is most helpful to the undersigned attorney. The patent has been carefully considered but is not believed to anticipate or render obvious the presently claimed invention. All of the claim limitations need to be

present in the patent and they are not. As noted at column 4 of the patent, the method and apparatus according to the invention are especially suitable for metering of very small quantities of poorly flowable powder mixture consisting of previously ground and/or sifted lactose and formoterol. The active ingredient is mixed with the lactose to form a powdered mixture and the powdered mixture is inhaled. A specific apparatus is used to create vibrations which cause the pellet to be substantially rounded, see for example line 66 of column 4.

Applicant is well aware of the Boesch reference which is specifically cited at the top of page 5 of Applicant's specification. As discussed in the paragraph bridging pages 4 and 5 of Applicant's specification, lactose pellets may be prepared by dry or wet pelleting methods known in the art. Thus, for example, microfine lactose particles may be dry pelleted using a tumbling or agitation process known as balling, for example as described in U.S. Patent 5,143,126. Further descriptions of making the lactose pellets are further described.

In accordance with the presently claimed aspect of the invention and as noted at page 5, line 21 of Applicant's specification, once formed, that is the lactose pellet is preformed and the lactose pellets may be mixed with microfine particles of one or more medicaments, optionally together with one or more conventional pharmaceutically acceptable ingredients, using conventional techniques to prepare the powder compositions according to the invention.

In order to avoid any ambiguity, Applicant has further amended claim 18 to specify that the lactose pellet is preformed in accordance with the present invention and in clear contrast to the simultaneous formation of the pellet in the presence of formoterol and lactose as required by the Boesch reference. Accordingly, it is most respectfully requested that the anticipation rejection be withdrawn.

The rejection of claims 18-39 under 35 U.S.C. 103 as being unpatentable over Boesch et al. as discussed in the anticipation rejection and further in view of the comments in the Official Action has been carefully considered but is most respectfully traversed.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP. Section 2143 states that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

The Official Action recognizes that Boesch et al. do not teach all of the specific drugs claimed by Applicant. However, Boesch et al. teach one of the specific drugs, formoterol. Furthermore, it is urged that one of skill in the art would be motivated to use any drug which can be administered through inhalation and in which benefits from good flow properties. Absent a teaching of equivalency in a reference, this represents hindsight and is impermissible. In re Fritch, 23 USPQ 1780, 1784(Fed Cir. 1992) ("It is impermissible to engage in hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps.).

Lastly, it is the position of the Examiner that Boesch teach Applicant's generic concept which <u>is combining lactose particles and active particles then creating larger formed pellets are agglomerated in order to create a better flowing formulation which can be used in inhalation therapy</u>. (Emphasis added.) This rejection and the comments in the Official Action, including the characterization of Applicant's invention

is specifically traversed. Where is there any disclosure in Applicant's specification concerning the generic concept referred to in the Official Action? Moreover, Applicant's specification may not be used as a teaching reference to combine the references and hindsight is not the proper standard of obviousness under 35 U.S.C. 103.

See also, process claims 29 and 30. Where is there any suggestion of this type of process in the Boesch et al reference? The further limitations of the dependent claims cannot be ignore and references must be cited to provide a tenable rejection. Certainly, relying on Applicants' specification for such a teaching is impermissible. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

In view of the above amendments to the claims an early and favorable action on the application is now in order and is most respectfully requested.

Respectfully submitted,
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REF/kdd
A02.wpd

November 5, 2001

Marked-Up Version Showing Changes Made

IN THE CLAIMS:

Please replace claim 18 with amended claim 18 as follows.

18(Amended). A pharmaceutical powder composition suitable for inhalation comprising microfine particles of medicament and at least one preformed lactose pellet having a diameter of from about 10 to about 1500 micrometers, which pellet comprises a plurality of microfine lactose particles, wherein the medicament is selected from the group consisting of codeine, dihydromorphine, ergotamine, fentanyl, morphine, diltiazem, cromoglycate, ketotifen, nedocromil, cephalosporins, penicillins, streptomycin, sulphonamides, tetracyclines, pentamidine, methapyrilene, budenoside, flunisolide, tipredane, triamcinolone acetonide, noscapine, ephedrine, adrenaline, fenoterol, formoterol, isoprenaline, metaproterenol, phenylephrine, phenylpropenolamine, pirbuterol, reproterol, rimeterol, terbutaline, isoetharine, tulobuterol, orciprenaline, (-)-4-amino-3,5-dichloro-a-[[[6-[-2-(2-pyridinyl)ethoxy]hexyl]-amino]methyl]benzenemethanol, amiloride, ipratropium, atropine, oxitropium, cortisone, hydrocortisone, prednisolone, aminophylline, choline theophyllinate, lysine theophyllinate, theophylline, insulin, glucagon and any mixtures thereof.

Please replace claims 22, 23 35 and 38 with the following replacement claims 22 and 23.

22(Amended). A pharmaceutical powder composition according to claim 21, wherein the soft lactose pellet has a crushing weight of about 50 to about 500 mg [as determined by the crushing test described herein].

23(Amended). A pharmaceutical powder composition according to claim 22, wherein the soft lactose pellet has a crushing weight of about 50 to about 100 mg [as determined by the crushing test described herein].

35(Amended). A pharmaceutical powder composition according to claim 34, wherein the soft lactose pellet has a crushing weight of about 50 to about 500 mg [as determined by the crushing test described herein].

38(Amended). A pharmaceutical powder composition according to claim 18, wherein said at least one lactose pellet has a diameter form about 150 to 1000 micrometers and wherein at least about 90% by way of the microfine particles of lactose have a diameter of less than about 15 micrometers and wherein the lactose pellet is a soft lactose pellet having a crushing weight of about 50 to about 150 mg [as determined by the crushing test described herein].